

**Training Workshop: Assessment of the Quality Part of the Dossier —  
WHO Prequalification of Medicines Programme**

**Copenhagen, Denmark  
January 19-22, 2011**

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***Trip Report***

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**PROMOTING THE QUALITY OF MEDICINES**

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## **About PQM**

The Promoting the Quality of Medicines (PQM) program, funded by the U.S. Agency for International Development (USAID), is the successor of the Drug Quality and Information (DQI) program implemented by the United States Pharmacopeia (USP). PQM is USAID's response to the growing challenge posed by the proliferation of counterfeit and substandard medicines. By providing technical assistance to developing countries, PQM helps build local capacity in medicine quality assurance systems, increase the supply of quality medicines to priority USAID health programs, and ensure the quality and safety of medicines globally. This document does not necessarily represent the views or opinions of USAID or the United States Government. It may be reproduced if credit is given to PQM and USP.

## **Executive Summary**

PQM staff (Dr. Souly Phanouvong and Mr. David Vanscoy) traveled to Copenhagen, at the invitation of the World Health Organization (WHO) Prequalification Team, to participate in the *Training Workshop: Assessment of the Quality Part of the Dossier*. The workshop helped increase PQM's knowledge of key dossier requirements, some commonly encountered deficiencies, and how to provide better technical assistance to manufacturers interested in pursuing WHO prequalification for second-line tuberculosis (TB) medicines.

## **Source of Funding**

This trip was supported with Core Funds for TB.

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## ACRONYMS

ATB	Anti-Tuberculosis Medicines
CTD	Common Technical Document
DQI	Drug Quality and Information Program
FPP	Finished Pharmaceutical Product
GMP	Good Manufacturing Practices
MDR-TB	Multi-Drug Resistant Tuberculosis
PQM	Promoting the Quality of Medicines Program
QIS	Quality Information Summary
QOS-PD	Quality Overall Summary – Product Dossier
TB	Tuberculosis
USAID	United States Agency for International Development
USP	United States Pharmacopeia
WHO	World Health Organization
WHO PQ	World Health Organization Prequalification Programme

## **Background**

Despite efforts by the World Health Organization Prequalification program (WHO PQ), Global Drug Facility, and the Green Light Committee to increase access to essential anti-tuberculosis medicines (ATBs), there are not enough WHO-prequalified second-line ATBs and manufacturers available. There is also an inadequate supply of products to treat patients with multi-drug resistant TB (MDR-TB). DQI (now PQM) has been assisting in efforts to increase the availability of good quality second-line ATBs. To expedite the prequalification process and thereby expand the pool of viable manufacturers, PQM is providing technical assistance to interested companies to:

- Prepare their product dossiers for submission to the WHO prequalification program in a manner that fulfills the requirements.
- Facilitate discussions with WHO to remedy incomplete dossiers or to respond to WHO comments.
- Guide manufacturers onsite to comply with the principles and guidelines of WHO Good Manufacturing Practices (GMP) and the requirements of the prequalification program.

## **Purpose of Workshop**

- Increase knowledge of key dossier requirements
- Learn about some commonly encountered deficiencies and how to address them
- Learn how to provide better technical assistance to manufacturers interested in pursuing WHO prequalification for second-line ATBs
- Learn about the Common Technical Document (CTD), a new format for the preparation of product dossiers

## **Training Workshop: Assessment of the Quality Part of the Dossier**

The following bullet points outline the key themes of the training workshop:

- Introduction of the CTD
- Introduction of Document 10.375 *Guideline on Submission of Documentation for a Multisource (Generic) Finished Pharmaceutical Product (FPP): Preparation of Product Dossiers (PDS) in Common Technical Document (CTD) Format*. This is known as the “preparation guideline.”
- In-depth review of the revised Document 10.373 *Guideline on Submission of Documentation for a Multisource (Generic) Finished Pharmaceutical Product (FPP): Quality Part*. This included the revised Quality Overall Summary – Product Dossier (QOS-PD) and the revised Quality Information Summary (QIS).
- Several presentations on common problems associated with dossier submission and review, such as establishing impurity specifications, dissolution studies, High Performance Liquid Chromatography method validation, and stability requirements.

## **Workshop Activities**

### **January 19-22, 2011**

The workshop was attended by 37 participants representing regulatory agencies and programs from several countries. After brief introductions by Dr. Stahl and the participants, senior assessors of the WHO PQ (Linda Palahniuk, Wondiyfraw Worku, Satish Mallya, Anthony Fake,

Hua Yin, and Theo Dekker) led the training based on their respective areas of expertise (see *Annex 1* for the agenda and *Annex 2* for the full list of participants). The training covered the background of prequalification to drug development and final medicinal products. Participants were given an opportunity to review and provide solutions to different case study scenarios, and one-on-one meetings with the trainers were held on the last day of the workshop.

**Key benefits the PQM staff received from this training workshop:**

1. Latest updates on WHO PQ guidelines
2. Familiarization with the new dossier format and presentation (CTD), especially the QIS/QOS formats and templates
3. Clarifications on many practical issues PQM staff have encountered while providing technical assistance to manufacturers
4. Interaction with assessors of WHO PQ for specific questions and improved communications

**Workshop Materials**

Workshop slide presentations can be obtained online at <http://apps.who.int/prequal/> or upon request from PQM staff ([SXP@usp.org](mailto:SXP@usp.org)).



## **Annex 1: Workshop Agenda**

### **Wednesday January 19, 2011**

- 8:30-8:45: Welcome and introduction: Matthias Stahl
- 8:45-9:00: Training session outline and objectives: Lynda Paleshnuik
- 9:00-10:00: Prequalification: Overview and update of PQP: Wondiyfraw Worku
- 10:00-10:20: Break
- 10:20-11:10: The new PQP quality guidelines: Lynda Paleshnuik
- 11:10-12:10: API assessment: Approaches and considerations: Antony Fake
- 12:10-13:10: Lunch
- 13:10-14:00: QIS/QOS: The new PQP quality templates: Lynda Paleshnuik
- 14:00-14:20: Break
- 14:20-15:20: Impurities: Establishing specifications (Q3A/B, qualification, etc): Antony Fake
- 15:20-16:20: The ICH Q8 “Minimal approach” to pharmaceutical development: Satish Mallya
- 16:20-17:00: Open discussion/Q&A on the day’s topics
- 19:00: Informal dinner

### **Thursday January 20, 2011**

- 8:30-8:45: Questions on Day 1 Material
- 8:45-10:10: Dissolution case studies: Theo Dekker
- 10:10-10:30: Break
- 10:30-11:30: Supporting documents for assessment - SUPAC: Lynda Paleshnuik
- 11:30-12:30: FPP assessment: Approaches and considerations: Wondiyfraw Worku
- 12:30-13:30: Lunch
- 13:30-14:30: Method and validation basics – HPLC case study: Hua Yin
- 14:30-14:50: Break
- 14:50-15:50: Formulation development issues: solid orals: Satish Mallya
- 15:50-16:30: Stability: Rutendo Kuwana
- 16:30-17:00: Open discussion/Q&A on the day’s topics

### **Friday January 21, 2011**

- 8:30-8:45: Questions on Day 2 Material
- 8:45-9:15: GMP lessons for quality review: Rutendo Kuwana
- 9:15-10:40: Assessing production documents: executed and master records: Satish Mallya
- 10:40-11:00: Break
- 11:00-12:00: Workshop evaluation/One-on-one breakout sessions begin
- 12:00-13:00: Lunch
- 13:00-16:45: Workshop evaluation/One-on-one breakout sessions continue

### **Saturday January 22, 2011**

- 9:00-11:45: Written examination on workshop topics
- 11:45-12:00: Formal meeting close

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